INSTITUTIONAL REVIEW BOARD (IRB)
REQUEST FOR RAPID ASSESSMENT PROTOCOL APPROVAL

Date Rec'd in HSO _____

Instructions: Use this form when requesting rapid review of your protocol. Please submit this form electronically and attach, when applicable, a consent form, child's assent form, phone scripts, recruitment fliers, medical records release, and questionnaire (or types of questions, i.e., sensitive/nonsensitive, if an instrument is under development), to the CIO designated staff official. However, if submitted in hardtop, please send the original and seven copies of all documents to the CIO designated staff official. Consecutively number **ALL** pages, beginning with the title page of the protocol, followed by any consent form(s) and ancillary documents. Complete all applicable items or the form will be returned.

Date Submitted: _____

PROTOCOL NO. _____
(For Human Subjects Office Use)

Title of Protocol: _____

Name of CDC Employee Serving as Principal Investigator (PI) and Degrees:

_____

Scientific Ethics Verification No.: _____

Work Phone: _____ Fax: _____

Home Phone: _____ Fax: _____

CIO: _____ **Division**: _____ **MS**: _____

Email Address: _____

Names of CIO Contact Persons if PI (above) is Not Available (Write in "Same as Above" if applicable):

_____

Telephone Nos.:
Work: _____

Email Address: _____

Home: _____

Scientific Ethics Verification No.: _____

Name of CDC Co-PI or Supervisor and Degrees:

_____

Work Telephone No.: _____

Email Address: _____

Work FAX No.: _____

Scientific Ethics Verification No.: _____

Study Population (If an international study, provide race/ethnicity of subjects by percentage):

_____

_____ Estimated number of subjects

For individuals who were enrolled this year:
Gender distribution:
_____ % Female _____ % Male

Race/ethnicity distribution estimate for domestic studies:

_____ % American Indian or Alaskan Native
_____ % Asian or Pacific Islander
_____ % Black or African American, not of Hispanic origin
_____ % Hispanic
_____ % White, not of Hispanic Origin

Vulnerable Populations - Do subjects include: _____ YES _____ NO
If YES, check all that apply

_____ Pregnant women and/or fetuses as a SPECIFIC targets group (Ref: 45CFR46, Subpart B)

_____ Prisoners (Ref: 45CFR46, Subpart C)

_____ Children 17 years of age or younger (Ref: 45CFR46, Subpart D)
_____ If YES, are you requesting a waiver of parental permission?

_____ Mentally disabled

_____ Educationally or economically disadvantaged

STUDY DESIGN ISSUES (check all that apply)

_____ Will CDC investigators have personal identifiers?

_____ Is a waiver or alteration of informed consent being requested in this project? (Ref: 45CFR46.116)

_____ Is a waiver of documentation of consent, being requested for this project? (Ref: 45CFR46.117)

_____ If specimens are collected, will they be stored for future use?

_____ Is HIV testing being performed as part of the study?

_____ Is genetic testing planned?

_____ Is this an outbreak investigation with a research question?

_____ Does the study involve the use of a drug or device in an emergency situation? (See FDA Regulations)
_____ If YES, will the study be carried out under an Investigational New Drug (IND) or device (IDE)?

FUNDING (check one)

_____ PGO Funding Mechanism Used:

_____ Cooperative Agreement No(s).: _____

_____ Contract No(s).: _____

_____ Grant: _____

_____ Purchase Order (a.k.a. Simplified Acquisition): _____

_____ Other funding mechanism:

_____ Memorandum of Understanding (MOU) (With whom): _____

_____ Interagency Agreement (IAA) (Name of other agency): _____

_____ Other (Specify type and with whom): _____

_____ Only CDC investigators performing study

_____ Collaborative (Non-CDC investigators & CDC investigators; no funding involved)

LOCATION OF THIS RESEARCH (Use additional sheets if necessary)

_____ U.S. or its territories? _____ Foreign country (countries)?

List All Collaborating Sites by Full Name and Location (include state):	**OPRR Assurance No.**
1.	
2.	
3.	
4.	
5.	

DATA CONFIDENTIALITY INFORMATION			**REFERENCES:**		
Does CDC have an Assurance of Confidentiality to cover this project?	YES	NO	Applied For	N/A	§ 308(d) PHS Act
Does the local site(s) have a Certificate of Confidentiality to cover this project?	YES	NO	Applied For	N/A	§301(d) PHS Act

Summary of the public health problem that the project will address:

Research question for this project:

Objectives for this research:

Setting(s) for, and the circumstances of, participant recruiting:

Summary of the procedures of this research and their degree of risk:

Risk of the research (physical, psychological, social):

Benefits for study participants:

Information handling (i.e., security and confidentiality) and specimen handling:

Reasons and details, if consent needs to be waived or altered (otherwise, write "Not Applicable" in the space below:

Details of identity linkage and the feedback of results, if samples are being stored (otherwise, write "Not Applicable" in the space below):

Approvals (Signature and Position Title): Branch Chief:	**Date:**	**Remarks:**
Division Director:		
CIO Human Subjects Contact:		